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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,596	02/18/2004	Robert Falotico	CRD-5065	3367

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EXAMINER	
PELLEGRINO, BRIAN E	

ART UNIT	PAPER NUMBER
3738	

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07/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,596	FALOTICO ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robida (2005/166841). Figs. 2,3 show a stent. Robida also discloses (paragraph 54) other medical devices, such as stent grafts and devices capable of being an anastomosis device. Robida discloses that the device is to be coated with drugs and can include combinations of rapamycin and cladribine, paragraphs 56,61. Robida additionally discloses the therapeutic agents are combined in a polymer material, paragraph 62. Robida discloses the polymer can be an acrylic, paragraphs 62,63. Robida also discloses that the device can be coated with multiple layers and have different polymers, paragraph 67. However, Robida does not explicitly disclose the concentration of cladribine having a range of about 56 nano-molar to 900 nano-molar. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use cladribine with a concentration within the range between about 56 nano-molar to 900 nano-molar, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopia et al. (WO 01/87372) in view of Morris et al. (5516781). Kopia et al. disclose a stent coated with a polymer having a combination of drugs, including rapamycin and

another drug, page 7, lines 14-17,22-30. Kopia does disclose multiple antiproliferative drugs, such as rapamycin and cladribine, page 7, line 17. Table 2 illustrates the stent has a basecoat and a topcoat. The device could be construed as a stent-graft since it includes coatings. The device also could function as an anastomosis implant. Please note the intended use carries no weight in the absence of any distinguishing structure. However, Kopia does not explicitly disclose the combination of rapamycin and cladribine or the concentration of cladribine having a range of about 56 nano-molar to 900 nano-molar. Morris et al. teach that rapamycin can be combined with other antiproliferative drugs to treat vascular disease, col. 4, lines 10-22. It would have been obvious to one of ordinary skill in the art to combine antiproliferative agents as taught by Morris et al. and use the two antiproliferatives combined such as cladribine and rapamycin on the stent of Kopia to obtain a synergistic effect to reduce or prevent restenosis. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use cladribine with a concentration within the range between about 56 nano-molar to 900 nano-molar, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopia et al. (WO 01/87372) in view of Morris et al. '781 as applied to claim 1 above, and further in view of Ragheb et al. (2003/36794). Kopia '372 as modified by Morris '781 is explained above. However, Kopia in view of Morris fail to disclose the polymers used for the coating as fluoropolymers and acrylics. Ragheb et al. teach the use of acrylic

polymers (paragraphs 74-76) and fluoropolymers (paragraphs 22,53,115) with a rapamycin stent, paragraphs 17,63,65. It would have been obvious to one of ordinary skill in the art to substitute polymers and utilize fluoropolymers and acrylics as taught by Ragheb et al. with the stent of Kopia '372 as modified by Morris '781 such that it provides inert coatings that are separate and distinct in order to provide different release rates.

Response to Arguments

Applicant's arguments filed 4/1/09 have been fully considered but they are not persuasive. Applicants argue that the rejection over Robida is improper for not being obvious to combine the drugs rapamycin and cladribine as found in a list of therapeutic agents by Robida. Applicants argue that because the drugs claimed are from a "laundry" list disclosed by Robida, it is not obvious to one of ordinary skill to select both rapamycin and cladribine from the list disclosed by Robida to form the claimed invention. However, MPEP 2131.02 states that because it is possible to envisage the combination of drugs used (Robida paragraph 61 discloses a combination) one of ordinary skill in the art is clearly capable of selecting two known drugs (paragraph 56) as listed and using them as claimed for their treatment effects. Applicants fail to provide any evidence that such a combination cannot be envisaged by the disclosure of Robida.

In response to applicant's argument that there is no suggestion to combine the drugs disclosed by the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the

claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Kopia and Morris disclose that combinations of drugs can be utilized for their particular treatment effect. As mentioned above both claimed drugs are disclosed by Kopia and Morris teaches that two antiproliferative drugs can be combined for a synergistic effect. Thus, one of ordinary skill in the art would clearly envisage combining two known drugs as disclosed in treatment regimen to provide the patient with the ability to prevent restenosis as is known by the drugs of rapamycin and cladribine.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738